

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of digital painting on 6-12 years old children's preoperative anxiety

Protocol summary

Study aim

Investigating the effect of digital painting on preoperative anxiety in children

Design

A randomized controlled clinical trial on 60 patients. The rand function of Excel software is used for randomization.

Settings and conduct

This study will be conducted in Bo Ali Hospital, Sari. Before surgery, all children will be present with their mother for 15 minutes in a room located within the operating room. During this time, the child in both groups will not receive any medicine. According to the allocation of each person's group, the intervention is carried out. The assessment of anxiety before and after the intervention will be done by another person who is not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 6 to 12 years
Exclusion criteria: No history of previous surgery

Intervention groups

The software under the Android "Coloring and Learn" made by "Orange Studios Games", which is downloaded from Cafe Bazaar and installed on the tablets, and the program will be given to the child while it is running on the tablet, and from the 30 ready images in this software. First, the child will be taught how to choose and color by the researcher, and then the child will be allowed to choose as many pictures as he wants and color as he wants. The duration of coloring will be 15 minutes. No intervention is performed in the control group.

Main outcome variables

Child anxiety, Mother Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110430006342N14**

Registration date: **2023-04-07, 1402/01/18**

Registration timing: **prospective**

Last update: **2023-04-07, 1402/01/18**

Update count: **0**

Registration date

2023-04-07, 1402/01/18

Registrant information

Name

Ali Asghar Ghods

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1335 4192

Email address

aaghods@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of digital painting on 6-12 years old children's preoperative anxiety

Public title

Investigating the effect of digital painting on anxiety

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 6 to 12 years old Ability to verbally communicate Ability to painting Informed consent of parents and children to participate in the study
Exclusion criteria:
 Presence of acute and chronic pain in the child mental retardation History of previous surgery cognitive and mental illness of children, as confirmed by parents

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples is done as a random block of four prepared using Excel software. A represents the test group and B represents the control group

Blinding (investigator's opinion)
Single blinded

Blinding description
The evaluating nurse enters the child's room before and after the intervention and measures the child's anxiety level using the m-YPAS anxiety questionnaire. He is not aware of the type of intervention. The intervention and control groups are marked with the letters A and B so that the statistician does not know the type of intervention

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Semnan University of Medical Sciences

Street address

Deputy of research and technology, Central Headquarters of Semnan University of Medical

Sciences, Basij Boulevard

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.SEMUMS.REC.1401.339

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

before and after intervention

Method of measurement

Completing the Modified Yale Preoperative Anxiety Scale (m-YPAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the software under the Android operating system called "Coloring and Learn" made by "Orange Studios Games" which is downloaded from Cafe Bazaar and installed on the tablets and the program will be given to the child while it is running on the tablet and from 30 ready images in In this software, the first picture is selected by the researcher and the child is taught how to color, and then the child will be allowed to choose as many pictures as he wants and color as he wants. The duration of coloring will be 15 minutes.

Category

Other

2

Description

Control group: There is no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bo Ali Sinai Hospital, Sari

Full name of responsible person

Mehrasa Mottaghi

Street address

Bo Ali Sinai Hospital, Sari

City

Sari

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Mazandaran

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-33556259

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

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majidmirmohammadkhani@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ali Asghar Ghods

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

Six months after the completion of sampling

To whom data/document is available

Officials of the research assistant and referees

Under which criteria data/document could be used

On request

From where data/document is obtainable

Ali Asghar Ghods aaghods@yahoo.com

What processes are involved for a request to access data/document

The request is reviewed and decided by the study team

Comments